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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/741,790	12/19/2003	Christopher C. Fraser	MPI00-535OMNICN1M	6648

30405 7590 06/08/2006

MILLENNIUM PHARMACEUTICALS, INC.
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CAMBRIDGE, MA 02139

EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/741,790	FRASER ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8-14,16 and 19-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-5, 8-14, 16 and 19-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's preliminary amendment filed on 03 November 2004 is acknowledged and entered. Following the amendment, the original claims 6, 7, 15, 17, 18 and 26-85 are canceled, and claims 1, 2, 8, 9 and 12 are amended.

Currently, claims 1-5, 8-14, 16 and 19-25 are pending.

Amendment Format

Applicants amendment of claims is not in compliance with the "Revised Format of Amendment" as the deleted matter in the amended claims 1, 2, 8, 9 and 12 is shown in brackets. According to the "Revised Format of Amendment", all claims being currently amended must be presented with markings to indicate the changes that have been made relative to the immediate prior version, and the changes in any amended claim should be shown by ***strikethrough (for deleted matter)***, or underlining (for added matter).

Applicants are required to follow the guidelines set forth in the "Revised Format of Amendment" for the future claim amendment.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 12, drawn to isolated nucleic acid molecules, a vector containing same, a host cell thereof, and a recombinant method for producing the encoded polypeptide, classified in class 435, subclass 69.1.

II. Claims 8-10, drawn to isolated polypeptides, classified in class 530, subclass 350.

III. Claims 11, 23 and 24 drawn to antibodies specific to said polypeptides, and a method of making thereof, classified in class 530, subclass 387.9.

IV. Claims 13 and 14, drawn to a method for detecting the polypeptide, classified in class 435, subclass 7.1.

V. Claim 16, drawn to a method for detecting a nucleic acid molecule, classified in class 435, subclass 6.

VI. Claims 19 and 20, drawn to a method for identifying a compound binding with a polypeptide, classified in class 436, subclass 501.

VII. Claim 21, drawn to a method for modulating the activity of a polypeptide, classified in class 435, subclass 7.1.

VIII. Claim 22, drawn to a method for identifying a compound modulating the activity of a polypeptide, classification depending upon the method steps.

IX. Claim 25, drawn to a method of making an antibody substance by contacting the polypeptide with a plurality of particles comprising an antibody and a nucleic acid encoding thereof, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because:

The nucleic acid of Invention I is related to the polypeptide of Invention II by virtue of encoding same. The nucleic acid molecule has utility for the recombinant production of the protein in a host cell. Although the nucleic acid molecules and proteins are related since the nucleic acid encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the nucleic acid may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The method of Invention I is related to the polypeptide of Invention II as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the products as claimed may be isolated from their natural source or made by chemical peptide synthesis.

The products of Invention I are distinct from and unrelated to the antibody of Invention III because they are physically and functionally distinct chemical entities which share neither structure nor function. The method of Invention I is distinct and unrelated from the antibody of Invention III because the antibody may be neither made by nor used in the methods.

Invention I is distinct from and unrelated to Inventions IV and VI-IX, wherein the nucleic acid of Invention I is neither made by nor used in the methods of Inventions IV and VI-IX, and wherein each does not require the other.

Invention I is related to Invention V as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for the production of the polypeptide of Invention I.

The polypeptide of Invention II is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the protein.

Invention II is distinct from and unrelated to Inventions IV and V, wherein the polypeptide of Invention II is neither made by nor used in the methods of Inventions IV and V, and wherein each does not require the other.

Invention II is related to Inventions VI-IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed may be used for generating antibody of Invention III.

Invention III is related to Invention IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the product as claimed may be used for the purification of the polypeptide of Invention II.

Invention III is distinct from and unrelated to Inventions V-IX, wherein the antibody of Invention III is neither made by nor used in the methods of Inventions V-IX, and wherein each does not require the other.

Inventions V-IX are drawn to independent methods, wherein each of the methods has different process steps, different active agents, different starting and ending points, and/or is for a different purpose, such that they require separate searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

2. Furthermore, regardless of which Invention applicants elect above, further **restriction** is required under 35 U.S.C. 121:

A. Elect *one* specific nucleic acid sequence with SEQ ID NO, and/or ATCC accession number from the nucleotide sequences listed in claim 1, part a), and indicate the corresponding amino acid sequence with SEQ ID NO.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs/ATCC number represents a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of the invention from Groups I-IX, and an election of the invention from Group A, to be examined even though the requirement be traversed (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention. Applicant is advised that neither I-IX nor A is species election requirement; rather, each of I-IX and A is a restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected

process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dong Jiang, Ph.D.
Patent Examiner
AU1646
6/2/06